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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,191	07/16/2002	Anand Achanta	C75103	1515

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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,191	ACHANTA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-27,29,35,38-40,62-73,77-84,86-101,104 and 105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27,29,35,38-40,62-73,77-84,86-101,104 and 105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment, and Request for Extension of Time filed 09/07/04.

Specification

The disclosure is objected to because contains drawings. See 37 C.F.R. § 1.84(h). Applicant is suggested to submit drawings on a separate sheet.

Appropriate correction is required.

Claim Objections

Claim 78 is objected to under 37 CFR 1.75(c), as being of improper dependent form. It is suggested to amend the claim to correct the typographical error in line 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-27, 29 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshlack et al. US 5,472,712.

Oshlack discloses a stabilized solid controlled release formulation comprising substrate, such as beads (beadlet), pellets, or spheroids of active agents being coated

with aqueous dispersion of hydrophobic polymer to obtain a weight gain of from about 2 to about 25% (abstract and column 6, lines 20-42). The aqueous dispersion of hydrophobic polymer is a dispersion of ethyl cellulose, such as Aquacoat® or Surelease® (column 8, lines 47-66, and examples). The substrate coated with active agents can be protected with a barrier coating of hydroxypropylmethyl cellulose (HPMC) (column 9, lines 32-67). The active agents can be selected from therapeutically active agents, including dextromethorphan (column 14, line 50). The formulation further comprises an additional dose of active agent in an overcoating coated on the outer surface of the controlled release coating (immediate release coating) (column 16, lines 64 through column 17, lines 1-6).

The examiner notes that the cited reference does not teach the glass transition point of the ethyl cellulose dispersion. However, it is the examiner's position that the particular glass transition temperature is inherent because the reference teaches the use of the claimed ethyl cellulose dispersion, namely, Surelease®.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24-27, 29, 35, 38-40, 62-73, 77-84 and 86-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. US 5,133,974, in view of Adusumilli et al. US 5,595,758.

Paradissis discloses a sustained release formulation comprising from 0-50% of an immediate release particle containing core of at least one drug and up to 100% of an extended release particle, which contains the immediate release particle coated with a dissolution modifying system and optionally additional drug (column 3, lines 62-68). The core containing from about 4 to about 85% of drug includes dextromethorphan (abstract, column 4, lines 60-66, column 5, lines 8-11, and claims 1, 2, 18-20, and 29). The active core is being coated with from about 2 to about 35% of dissolution modifying system coating containing ethyl cellulose (column 6, lines 19-27). The coated particles can then tabletted or filled in gelatin capsules (column 9, lines 9-24).

Paradissis does not teach combination of drug as claimed in claim 77.

Adusumilli teaches gelatin capsule comprising combination of immediate release and sustained release drug particles selected from analgesic/decongestant, antihistamine/decongestant, decongestant/anti-tussive, decongestant/anti-tussive/antihistamine, and the like (column 5, lines 62 through column 7, lines 1-2). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release formulation of Paradissis using the combination of drugs in view of the teaching of Adusumilli with the motivation of providing an oral dosage containing sustained release and immediate release of combination of drugs useful for the treatment of cold and sinus.

Claims 24-27, 29, 38-40, 68-70, 78, 80-84 and 86-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. US 5,472,712, in view of Sparks et al. US 4,940,588.

Oshlack is relied upon for the reason stated above. Oshlack does not teach polyvinyl alcohol as a seal coat. However, Oshlack teaches any film-former known in the art may be used in a barrier protected coating layer (column 9, lines 61-63). Oshlack further teaches the use of plasticizer (column 7, lines 60 through column 8, lines 1-12).

Sparks teaches discrete micro-particle having average size of from 0.1 to 125 μm is being coated with film-forming polymer such as polyvinyl alcohol (column 3, lines 1-62). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release formulation of Oshlack using polyvinyl alcohol in a barrier coating because Sparks teaches polyvinyl alcohol is a known film-forming polymer. The expected result would be a sustained release dosage form suitable for administering phenylpropanolamine, dextromethorphan, pseudoephedrine, and the like.

Claims 104 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. US 5,472,712, and Cornell US 4,233,288.

Oshlack is relied upon for the reason stated above. Oshlack does not teach coconut oil as a plasticizing agent. However, coconut oil is a well known plasticizer. To be more specific, Cornell teaches plasticizer is vegetable oil, such as coconut oil

(column 6, lines 7-8, and column 7, lines 6-8). Thus, it would have been obvious for one of ordinary skill in the art to modify the plasticizer of Oshlack using coconut oil, because Oshlack teaches the use of water-soluble and water-insoluble plasticizer.

Response to Arguments

Applicant's arguments filed 09/07/04 have been fully considered but they are not persuasive.

Applicant argues that the claimed process does not require a curing of the finished product to be under humidifying conditions. The claimed process also does not require a curing time of 2-3 days. Contrary to the applicant's argument, applicants' claims do not exclude the curing step taught by Oshlack et al. because of the transitional phrase "comprising of". The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited method steps. See, e.g., Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). The transitional term "comprising" in a method claim indicates that the claim is open-ended and allows for additional steps. Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Even if applicants use the transitional phrase "consisting essentially of" to contend that additional steps in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps would materially change the

characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Applicant argues that Oshlack et al. only coats the substrate with a 2 to about 30% of drug, in contrast, applicants can, and have coated the spheres with a much higher drug load (see example 10). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., higher drug load, or drug load of about 47%) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the glass transition temperature of the product was not as predicted by the manufacturer, and therefore, applicant dispute the Examiner contention that this is an inherent and readily determinable characteristic of an ethylcellulose dispersion. However, in response to applicant's argument, the burden is shifted to applicant to provide data supporting that the ethylcellulose, namely Surelease taught by Oshlack does not have the claimed glass transition, because products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Applicant argues that Oshlack does not teach micronized DXM. However, it is the position of the examiner that such limitation is clearly inherent because Oshlack teaches the aqueous dispersion of hydrophobic polymers used as coatings in the present invention may be used to coat substrates such as microspheres, beads, or other multi-particulate system (column 6, lines 20-25). Accordingly, when the substrates to be coated are in micron size, such as microspheres, the active agent coated onto the substrates should be at least the same size, if not smaller. When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fuisz et al., Ambergaonkar et al., and Mehta et al. are cited as being of interest for the teachings of controlled release dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600